FY 2013 BsUFA
FINANCIAL REPORT

REQUIRED BY THE

BIOSIMILAR USER FEE ACT OF 2012

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

EXECUTIVE SUMMARY

The Biosimilar User Fee Act (BsUFA) of 2012 requires the Food and Drug Administration (FDA) to report annually on the financial aspects of its implementation of the Act. Required under BsUFA, this report covers fiscal year (FY) 2013.

BsUFA specifies that the following two legal conditions must be satisfied each year for FDA to collect and spend biosimilar biological product user fees:

1. The fee amounts FDA may collect for each fiscal year must be provided in that year's appropriation acts, or otherwise made available for obligation for such fiscal year.

2. FDA must allocate a minimum of $20,000,000 of non-user fee appropriations multiplied by the adjustment factor applicable to that fiscal year, for the process for the review of biosimilar biological product applications.

FDA met the two legal conditions in FY 2013, and this report explains how these legal conditions were satisfied. The statements and tables in the report also provide data on biosimilar biological product user fee collections, expenditures, and carryover balances.

In FY 2013, FDA collected $6.5 million in BsUFA fees and carried a balance of $6.5 million forward to expedite the process for the review of biosimilar biological product applications in future fiscal years. Due to budget constraints including sequestration, the timing of the appropriations allocated to the Agency, and the timing of fee collections, in FY 2013, FDA supported the process for the review of biosimilar biological product applications solely with non-user fee appropriated funds.

FDA appropriations in FY 2013 supported 98 full-time equivalents (FTEs), including salaries and operational expenses to support the staff responsible for the process for the review of biosimilar biological product applications.

In FY 2014, FDA will spend BsUFA fees to continue enhancing the review of biosimilar biological product applications, including postmarket safety activities, and to continue improving communications to meet the performance goals associated with this program.

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BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Act (BsUFA) of 2012 [Title IV of the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112-144], authorizes FDA to collect user fees from the biosimilar biological product industry to augment appropriations FDA spends on the process for the review of biosimilar biological product applications. FDA spends fee revenues and appropriations to hire, support, and maintain personnel for the review of biosimilar biological product applications to help ensure that safe and effective biosimilar biological products reach the American public.

BsUFA establishes fees for certain activities relating to biosimilar biological product development, for certain types of applications and supplements for approval of biosimilar biological products, on establishments where approved biosimilar biological products are made, and on biosimilar biological products after approval (section 744H(a)(2), 744H(a)(3) and 744H(a)(4), respectively, of the FD&C Act).

There are three types of fees for activities in connection with biosimilar biological product development: the initial biosimilar biological product development (BPD) fee, the annual BPD fee, and the reactivation fee. Under BsUFA, an initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 5 days after FDA grants the first BPD meeting for the product, whichever occurs first. Under BsUFA, the initial BPD fee rate for a fiscal year is equal to 10 percent of the fee rate established under the Prescription Drug User Fee Act (PDUFA) for an application requiring clinical data for that fiscal year. A sponsor who has paid the initial BPD fee for a product is considered to be participating in FDA's BPD program for the product.

Once a sponsor has paid the initial BPD fee for a product, the annual BPD fee for the product is due on October 1 beginning in the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing, or discontinues participation in FDA's BPD program for the product. The annual BPD fee rate for a fiscal year is equal to 10 percent of the fee rate established under PDUFA for an application requiring clinical data for that fiscal year.

Finally, the reactivation fee is a fee to rejoin FDA's BPD program for a product. Specifically, if a sponsor has discontinued participation in FDA's BPD program for a product and wants to again engage with FDA on development of the product as a biosimilar, the sponsor must pay a reactivation fee to resume participation in the BPD program for that product. The reactivation fee is assessed when the sponsor submits an IND for an investigation that FDA determines is intended to support a biosimilar biological product application or within 5 calendar days after FDA grants the sponsor's request for a BPD meeting for the product, whichever occurs first. Annual BPD fees will resume beginning in the fiscal year after the fiscal year in which the reactivation fee was paid. The reactivation fee is equal to 20 percent of the fee rate established under PDUFA for an application requiring clinical data for that fiscal year.

In addition to the fees for biosimilar biological product development, under BsUFA, sponsors must also pay fees for certain marketing applications and supplements, and on biosimilar biological products and establishments. Application and supplement fees are due upon submission of the application or supplement. Establishment and product fees are due annually on October 1. Application, supplement, establishment, and product fee rates under BsUFA are equal to the application, supplement, establishment, and product fee rates under PDUFA, respectively.

In FY 2013, the first year of BsUFA, FDA collected BPD fees, but no biosimilar application, supplement, establishment, or product fees.

BsUFA requires FDA to submit a performance report and a financial report to Congress no later than 120 days after the end of each fiscal year. The FY 2013 BsUFA Performance Report that describes FDA's progress in meeting the performance goals referred to in section 401(b) of BsUFA was transmitted to Congress on January 30, 2014. This report is the FY 2013 BsUFA Financial Report, which addresses the implementation and use of biosimilar biological product user fees by FDA during the period October 1, 2012, through September 30, 2013.

As required by BsUFA, this report discusses the legal conditions that must be satisfied for FDA to collect and spend biosimilar biological product user fees each year and shows how FDA determined that it met those requirements. Additionally, this report presents summary statements of FY 2013 fee collections, carryover balances, obligations of user fees, as well as the total costs associated with the process for the review of biosimilar biological product applications paid from both user fees and appropriations.

MEETING THE LEGAL CONDITIONS FOR BIOSIMILAR BIOLOGICAL PRODUCT USER FEES IN FY 2013

BsUFA imposes two legal conditions that must be satisfied for FDA to collect and spend biosimilar biological product user fees. A summary of how each of these legal conditions was satisfied in FY 2013 is shown below. Detailed explanations and calculations are described in Appendix A.

First legal condition: The amount of user fees collected for each fiscal year must be specified in that year's appropriation acts, or otherwise made available for obligation for such fiscal year. Section 744H(e)(2)(C) of the FD&C Act, as added by BsUFA, made available for obligation BsUFA fees collected for FY 2013, beginning on October 1, 2012, and continuing until the date of enactment of an Act making appropriations through September 30, 2013, for the salaries and expenses account of FDA. The Consolidated and Further Continuing Appropriations Act, 2013 (Public Law 113-6), which the President signed on March 26, 2013, made appropriations through September 30, 2013, for the salaries and expenses account of FDA. It specified that $20,242,000 shall be derived from biosimilar biological product user fees, and that biosimilar biological product user fees collected in excess of this amount are also appropriated for FDA. Thus, in FY 2013, the first legal condition was satisfied.

Second legal condition: FDA may not spend BsUFA fees in a fiscal year unless it allocates a minimum of $20,000,000 in appropriated funds (excluding user fees), multiplied by the adjustment factor applicable to that fiscal year, for the process for the review of biosimilar biological product applications. The specified minimum level for FY 2013 is $20,000,000. In FY 2013, FDA allocated and obligated $28,040,547 in appropriated funds (excluding user fees) for the process for the review of biosimilar biological product applications, as defined in section 744G(13). Since FDA allocated and obligated more than the specified minimum amount in FY 2013, the second legal condition was satisfied.

USER FEE COLLECTIONS

BsUFA authorizes FDA to assess and collect user fees for certain activities relating to biosimilar biological product development; submission of specified applications and supplements; establishments that produce biosimilar biological products; and for biosimilar biological products after approval. Such fees may only be spent for the process for the review of biosimilar biological product applications.

Under BsUFA, biosimilar biological product user fees collected and appropriated, but not expended by the end of a fiscal year, continue to remain available for FDA to spend in future fiscal years, until expended.

In FY 2013, FDA collected BPD fees totaling $6,464,085.

USER FEE OBLIGATIONS

BsUFA fees may be expended solely for the process for the review of biosimilar biological product applications, as defined in BsUFA. Allowable and excluded costs for the process for the review of biosimilar biological product applications are described in Appendix D.

Due to budget constraints including sequestration, the timing of the appropriations allocated to the Agency, and the timing of fee collections, in FY 2013, FDA supported the process for the review of biosimilar biological product applications solely with non-user fee appropriated funds. Going forward, FDA anticipates spending all authorized and appropriated BsUFA user fees in addition to non-user fee appropriations to support the process for the review of biosimilar biological product applications.

CARRYOVER BALANCES

Under BsUFA, user fees collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA in future fiscal years. These funds are referred to as carryover balances. In FY 2013, FDA collected $6,464,085 in user fees, and this amount remained available at the end of the fiscal year.

COLLECTIONS REALIZED

Under BsUFA, the total amount of user fees collected for a cohort year must be provided in appropriation acts, or otherwise made available for obligation. In FY 2013, the appropriations language enacted in Public Law 113-6 appropriated all BsUFA fees collected for FY 2013; therefore, the first legal condition was met. Accordingly, because the second legal condition described on page 3 of this report was also met, the total amount of BsUFA fees collected for FY 2013 is available for allocation for the process for the review of biosimilar biological product applications.

RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

At the end of FY 2013, there were several claims on the carryover balance. FDA holds a reserve of $100,000 for potential refunds in future years. Additionally, the amount of collections appropriated for FY 2013, but sequestered under the Balanced Budget and Emergency Deficit Control Act of 1985, as amended by the Budget Control Act of 2011, totaled $319,165; these funds are unavailable for obligation.[1]

Table 1 provides a summary of carryover balances as of September 30, 2013. The FY 2013 carryover balance is $6,464,085, and the amount available inclusive of anticipated claims is $6,044,920.

TABLE 1: SUMMARY STATEMENT OF BIOSIMILAR BIOLOGICAL USER FEES CARRYOVER BALANCE AS OF SEPTEMBER 30, 2013

STATUS OF CARRYOVER FUNDS	AMOUNT
FY 2013 Carryover Balance	$6,464,085
Reserve for Refunds	($100,000)
Reserve for Sequestered FY 2013 Collections	($319,165)
Remaining Carryover Balance	**$6,044,920**

Numbers may not total precisely due to rounding to the nearest dollar

[1] This report provides information on user fee balances as of the end of FY 2013. We note that, after the end of FY 2013, Congress enacted legislation that makes the FY 2013 sequestered user fees available for obligation by FDA. See section 747 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2014 (Public Law 113-76).

TOTAL COSTS OF THE PROCESS FOR THE REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

Table 2 shows the costs for the process for the review of biosimilar biological product applications during FY 2013 by FDA organizational components. It depicts the full cost of the process for the review of biosimilar biological product applications paid from non-user fee appropriations. The table displays data for the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Office of Regulatory Affairs (ORA), and FDA Headquarters (HQ).

TABLE 2: TOTAL COSTS OF THE PROCESS FOR THE REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS AS OF SEPTEMBER 30, 2013

FDA COMPONENT	FY 2013
CDER	$24,759,346
CBER	$1,097,336
ORA	$0
HQ	$2,183,865
TOTAL PROCESS COSTS	**$28,040,547**
Obligations from Appropriations	$28,040,547
Obligations from Biosimilar User Fees	$0

Numbers may not total precisely due to rounding to the nearest dollar

As mentioned before, all of the $28,040,547 obligated in FY 2013 for the process for the review of biosimilar biological product applications, as defined in BsUFA, came from non-user fee appropriations.

The development of the costs associated with the process for the review of biosimilar biological product applications is described in more detail in Appendix E.

FULL-TIME EQUIVALENTS (FTES)

FTE is a measure of paid staff years devoted to the process for the review of biosimilar biological product applications. In FY 2013, FDA expended 98 FTEs for the process for the review of biosimilar biological product applications.

Table 3 presents total FTE levels that support the process for the review of biosimilar biological product applications by FDA organizational components for FY 2013. Staff from the shared services organization (i.e. facilities, procurement, IT services, etc.) are included in the FTE levels for the aforementioned components.

TABLE 3: TOTAL FTES DEVOTED TO THE PROCESS FOR THE REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS AS OF SEPTEMBER 30, 2013

ORGANIZATIONAL COMPONENT	FTES UTILIZED
CDER	87
CBER	4
ORA	0
HQ	7
TOTAL FTEs	98

Numbers may not total precisely due to rounding to the nearest dollar

For additional information on the costs associated with the review of biosimilar biological product applications, refer to the Total Costs of the Process for the Review of Biosimilar Biological Product Applications section, on page 9.

MANAGEMENT CHALLENGES FOR FY 2014

In FY 2013, FDA staff expended significant effort in reviewing submissions for biosimilar biological products in development and meeting with sponsors to discuss their biosimilar development programs. Challenges FDA faces in FY 2014 include meeting increasingly challenging performance goals and continuing to implement the new initiatives for the biosimilar biological product review process agreed to in BsUFA. For example, FDA will continue to develop the scientific, regulatory, and policy infrastructure necessary for the review of biosimilar biological product applications, such as regulation and policy development and development of standards for biosimilar biological products subject to review and evaluation. FDA will also continue to provide targeted advice to sponsors of biosimilar biological products in development through its BPD program.

FDA is committed to meeting the BsUFA performance goals—including goals for proprietary name review, major dispute resolutions, clinical holds, special protocol assessments, meeting management, and application review—in order to enhance the efficiency, quality, and predictability of the biosimilar biological product review process. Having the necessary resources will be essential to meeting these goals.

APPENDIX A: CONDITIONS FOR ASSESSMENT AND USE OF FEES

The FD&C Act, as amended by BsUFA, specifies two legal conditions that must be met each fiscal year for FDA to collect and spend BsUFA fees. A summary of these legal conditions was introduced on page 3 of this report. This appendix provides detailed descriptions of these conditions and explanations of how FDA met these conditions in FY 2013.

The **first legal condition**, provided in section 744H(e)(2)(A) of the FD&C Act states:

> Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation acts, or otherwise made available for obligation for such fiscal year.

Section 744H(e)(2)(C) of the FD&C Act made available for obligation BsUFA fees collected for FY 2013, beginning on October 1, 2012, and continuing until the date of enactment of an Act making appropriations through September 30, 2013, for the salaries and expenses account of FDA. The Consolidated and Further Continuing Appropriations Act, 2013 (Public Law 113-6), which the President signed on March 26, 2013, made appropriations through September 30, 2013, for the salaries and expenses account of FDA. It specified that $20,242,000 shall be derived from biosimilar biological product user fees, and that biosimilar biological product user fees collected in excess of this amount are also appropriated for FDA. Therefore, the first legal condition was satisfied for FY 2013.

The **second legal condition**, provided in section 744H(e)(2)(B) of the FD&C Act states:

> The fees authorized by this section shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of the process for the review of biosimilar biological product applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $20,000,000 multiplied by the adjustment factor applicable to the fiscal year involved.

The "adjustment factor applicable to a fiscal year" referred to in section 744H(e)(2)(B) is defined in section 744G(1) of the FD&C Act. It provides that the adjustment factor applicable to a fiscal year is the Consumer Price Index (CPI) for all urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items) of the preceding fiscal year divided by such Index for September 2011.

Accordingly, the second legal condition requires FDA to allocate a minimum of $20,000,000 in non-user fee appropriations, multiplied by the adjustment factor applicable to that fiscal year, for the costs of the process for the review of biosimilar biological product applications. For FY 2013, the applicable adjustment factor is 1 because the CPI for the preceding fiscal year, i.e., September 2011, was 147.658, and this number is both the numerator and the denominator of the adjustment factor for FY 2013. After applying the adjustment factor of 1,

the minimum appropriation spending level for the process for the review of biosimilar biological product applications for FY 2013 is $20,000,000.

FDA chose to use amounts obligated as a measure of allocations, since funds cannot be obligated if they are not first allocated. In FY 2013, FDA obligations from appropriations (excluding user fees) for the process for the review of biosimilar biological product applications was $28,040,547, which exceeded the required minimum of $20,000,000 by $8,040,547. Therefore, the second legal condition was satisfied, and the full amount of fees collected for FY 2013 will be retained for FDA to spend in subsequent fiscal years on the future cost of the process for the review of biosimilar product applications.

APPENDIX B: PROGRAM WAIVERS

BsUFA provides for a waiver of the application fee for the first biosimilar biological product application submitted by a small business or its affiliate. For purposes of this waiver provision, the term "small business" means an entity that has fewer than 500 employees, including employees of affiliates, and does not have a drug product that has been approved under a human drug application (as defined in section 735 of the FD&C Act) or a biosimilar biological product application (as defined in section 744G(4)), and introduced or delivered for introduction into interstate commerce. See section 744H(c) of the FD&C Act.

In FY 2013, FDA did not grant any waivers for BsUFA fees.

APPENDIX C: BSUFA FEE RATES AND NUMBER OF FEES PAID IN FY 2013

BsUFA established four fee types and directs FDA to set the BsUFA fee rates for each fiscal year as follows: (1) The initial and annual BPD fee rates for a fiscal year are equal to 10 percent of the fee rate established under PDUFA for an application requiring clinical data for that fiscal year; (2) the BPD reactivation fee is equal to 20 percent of the fee rate established under PDUFA for an application requiring clinical data for that fiscal year; and (3) the application, establishment, and product fee rates under BsUFA are equal to the application, establishment, and product fee rates under PDUFA, respectively.

Table 4 shows the user fee rates that FDA published for FY 2013.

TABLE 4: BIOSIMILAR BIOLOGICAL PRODUCT USER FEE CATEGORIES AND FEE RATES[2]

USER FEE CATEGORY	FY 2013 RATE
BPD Fees	
Initial BPD Fee	$195,880
Annual BPD Fee	$195,880
Reactivation Fee	$391,760
Application Fees	
Application requiring clinical data	$1,958,800
Application not requiring clinical data	$979,400
Supplement requiring clinical data	$979,400
Establishment Fees	$526,500
Product Fees	$98,380

[2] FDA published FY 2013 biosimilar biological product user fee rates on August 1, 2012, in the Federal Register -- http://www.gpo.gov/fdsys/pkg/FR-2012-08-01/pdf/2012-18712.pdf

APPENDIX D: ALLOWABLE AND EXCLUDED COSTS FOR THE PROCESS FOR THE REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

The FD&C Act, as amended, defines the term "process for the review of biosimilar biological product applications" and the costs that may be included in that process. Fees may only be spent for activities that are included in this definition, although fee-generating activities are only a small subset of the activities that are included in this definition. FDA identifies those activities that are applicable to the process for the review of biosimilar biological product applications in this appendix. In Appendix E, FDA describes how the costs for the process for the review of biosimilar biological product applications are developed, based on the allowable activities identified in this appendix.

BSUFA-RELATED COSTS

Permissible Activities

Section 744G(13) of the FD&C Act defines the term "process for the review of biosimilar biological product applications" to mean the following activities of FDA with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements:

(A) The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

(B) Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or which set forth in detail the specific deficiencies in such applications, and where appropriate, the actions necessary to place such applications in condition for approval.

(C) The inspection of biosimilar biological product establishments and other facilities undertaken as part of FDA's review of pending biosimilar biological product applications and supplements.

(D) Activities necessary for the release of lots of biosimilar biological products under section 351(k) of the Public Health Service Act.

(E) Monitoring of research conducted in connection with the review of biosimilar biological product applications.

(F) Postmarket safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities:

(i) Collecting, developing, and reviewing safety information on biosimilar biological products, including adverse-event reports.

(ii) Developing and using improved adverse-event data-collection systems, including information technology systems

(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

(iv) Implementing and enforcing section 505(o) of the FD&C Act (relating to post-approval studies and clinical trials and labeling changes) and section 505(p) of the FD&C Act (relating to risk evaluation and mitigation strategies).

(v) Carrying out section 505(k)(5) of the FD&C Act (relating to adverse-event reports and postmarket safety activities).

All costs represented by the above activities are collectively referred to in this report as costs for "the process for the review of biosimilar biological product applications."

Section 744G(9) of the FD&C Act defines the term "costs of resources allocated for the process for the review of biosimilar biological product applications" as the expenses in connection with the process for the review of biosimilar biological product applications for:

(A) Officers and employees of the FDA, contractors of FDA, advisory committees, and the costs related to such officers, employees, and committees, and to contracts with such contractors;

(B) Management of information, and the acquisition, maintenance, and repair of computer resources;

(C) Leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) Collecting fees under section 744H and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

EXCLUDED ACTIVITIES

BsUFA fees may not be spent on the following types of products that could be approved under an application for licensure under section 351(k) of the Public Health Service Act:

- Large volume parenteral drug products approved before September 1, 1992;
- Allergenic extract products;
- Whole blood or a blood component for transfusion ;
- In vitro diagnostic biologic products ;
- A biological product for further manufacturing use only;
- A bovine blood product for topical application licensed before September 1, 1992;and

- A product that is not distributed commercially, if application for licensure under section 351(k) is submitted by a state or federal government entity.

Excluded Process Activities

BsUFA fees may not be spent on the following types of activities:

- Enforcement policy development not related to sections 505(o) and (p) of the FD&C Act;
- Post-approval compliance activities not related to the enforcement of sections 505(o) and (p) of the FD&C Act;
- Advertising review activities once marketing of the product has begun;
- Inspections unrelated to the review of covered applications, unless undertaken for the enforcement of sections 505(o) and (p) of the FD&C Act; and
- Research unrelated to the process for the review of biosimilar biological product applications.

APPENDIX E: DEVELOPMENT OF COSTS FOR THEPROCESS FOR THE REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

GENERAL METHODOLOGY

The costs associated with the process for the review of biosimilar biological product applications are based on obligations recorded within CDER, CBER, ORA, and HQ. These organizations correspond to the cost categories presented as follows:

Cost Category	FDA Organization
Costs for the review of biosimilar biological product applications and supplements (including costs in connection with FDA's BPD program)	CDER and CBER
Field Inspection and Investigation Costs	ORA
FDA General and Administrative Costs	HQ

The costs for each component are shown in table 2 on page 9. They were derived utilizing time-reporting systems in CDER, CBER, and ORA, and were calculated for HQ as described in more detail in this appendix. Using the definitions of costs and activities included in the process for the review of biosimilar biological product applications in BsUFA, as explained in the discussion in Appendix D, the cost categories within each organization listed above were identified as parts of the biosimilar biological product review process.

CENTER COSTS

Costs associated with the process for the review for biosimilar biological product applications are tracked for each organizational component in CDER and CBER, usually at the division level. Most FDA components involved in the process perform a mixture of activities – some explicitly within the definition of the process for the review of biosimilar biological product applications, and some not. FDA groups its organizational components into three categories:

- direct review and laboratory
- indirect review and support
- Center-wide costs

The allocation of costs for each category is discussed below.

Direct Review and Laboratory

Employees in all components of CDER and CBER, other than those noted below as Center indirect review and support components, reported their time for eight weeks (two weeks per quarter) each fiscal year in activity-based time reporting systems. The activities in the systems differentiate between time spent on the process for the review of biosimilar biological product applications and all other time, so that time reported can be separated into allowable and excluded activities under BsUFA.

FDA is a payroll-intensive organization – about 52 percent of all FDA funds pay for employee salaries and benefits, and almost all other costs are directly supporting these employees. Thus, the average percentage of time reported on biosimilar biological product review process activities for CDER and CBER is then applied to all costs incurred for the entire fiscal year in those Centers. This method provides an estimate of each cost centers' costs incurred for the process of the review of biosimilar biological product applications.

Indirect Review and Support

Indirect review and support components provide the infrastructure for the review process. In CDER, these components include portions of the Office of the Center Director, the Office of Strategic Programs, the Office of Management, the Office of Communications, and the Office of Executive Programs. In CBER, these components include portions of the Office of the Center Director, Office of Management, and the Office of Communications, Outreach, and Development. Most employees of these components do not report their time.

FDA assumes the time of management and administrative personnel supporting the process for the review of biosimilar biological product applications is equivalent to the proportion of time Center employees in direct review and laboratory components spend on biosimilar biological product review process activities. Thus, the average percentage of time expended on biosimilar biological product review activities for all direct review and laboratory components in FY 2013 was applied to all costs incurred for the entire fiscal year by the indirect review and support components.

Center-Wide Costs

A number of Center-wide and FDA-wide expenses are paid from the central accounts of the Center or of FDA rather than from funds allocated to a specific Center or division or office within the Center. These costs include rent for facilities that house CDER and CBER staff, telecommunications and utility costs, some computer equipment and support costs, and costs of the Office of Shared Services, which supports all FDA programs and activities. A percentage of these Center and FDA-wide costs are chargeable to the process for the review of biosimilar biological product applications. That percentage is either a specific amount that is supported by independent documentation or is the amount of time reported for allowable activities (direct and indirect) in the Center, as a percentage of total time reported for all Center direct and indirect activities.

Resources expended in FY 2013 by the Office of Shared Services in supporting the process for the review of biosimilar biological product applications are reported as if they were incurred in CDER, CBER, ORA, or HQ.

FIELD INSPECTION AND INVESTIGATION COSTS

ORA incurs all field inspection, investigation, and laboratory analyses costs. ORA costs are incurred in both district offices (the "field") and headquarters offices, which are tracked in the Field Accomplishment and Compliance Tracking System (FACTS). FACTS is a time and activity tracking system that captures time spent in a variety of categories, including pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples, which are all part of the review process for biosimilar biological product applications.

Total direct hours reported in FACTS are used to calculate the total number of FTEs required by ORA to perform these activities. In addition to the direct time, an allocation of support time is also included to represent the work done by the ORA administrative and management personnel. FDA then multiplies the total number of FTEs used in the process for the review of biosimilar biological product applications by the average salary and benefits cost in ORA to arrive at ORA salary and benefit costs for work that is a part of the process for the review of biosimilar biological product applications, as defined in BsUFA. The final step is to allocate ORA obligations for operations and rent to the process for the review of biosimilar biological product applications, based upon the ratio of user fee related FTEs to total ORA FTEs.

In FY 2013, ORA did not incur any costs for the process for the review of biosimilar biological product applications.

FDA GENERAL AND ADMINISTRATIVE COSTS

FDA's general and administrative costs include all costs incurred in FDA's HQ that are attributable to the Office of the Commissioner and all other FDA headquarters components that are not Centers or the Office of Regulatory Affairs. For the purpose of these calculations, HQ is considered to comprise the following offices:

- Immediate Office of the Commissioner
- Office of the Counselor to the Commissioner
- Office of Legislation
- Office of Policy and Planning
- Office of External Affairs
- Office of the Executive Secretariat
- Office of the Chief Counsel
- Office of Minority Health
- Office of Women's Health Office of the Chief Scientist (excluding the National Center for Toxicological Research)
- Office of Operations
- Office of Foods and Veterinary Medicine (excluding the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine)

- Office of Medical Products and Tobacco (excluding CDER, CBER, the Center for Device and Radiological Health, and the Center for Tobacco Products)
- Office of Global Regulatory Operations and Policy (excluding ORA)

In summary, the HQ costs include all of FDA except for the six product-oriented Centers, ORA, and the National Center for Toxicological Research.

The HQ costs applicable to the process for the review of biosimilar biological product applications were calculated using a method prescribed by the Division of Cost Determination Management, Office of Finance, Office of the Secretary, Department of Health and Human Services. The method uses the percentage derived by dividing total HQ costs by the total FDA salary expenses (excluding benefits) after subtracting the salary expenses (excluding benefits) from HQ. That percentage is then multiplied by the total salaries (excluding benefits) applicable to the process for the review of biosimilar biological product applications in CDER, CBER, and ORA to derive the applicable FDA general and administrative costs.

Using this methodology, FDA dedicated $2,183,865 in general and administrative costs to the process of the review of biosimilar biological product applications in FY 2013. The costs are total costs obligated from non-user fee appropriations. FDA strives to maintain a low overhead cost for the process for the review of biosimilar biological product applications. General and administrative costs are approximately 7.8 percent of the total costs of the process for the review of biosimilar biological product applications in FY 2013.